UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: ALL CLASS ACTIONS	Judge Patti B. Saris

MEMORANDUM IN SUPPORT OF SCHERING-PLOUGH CORPORATION'S AND WARRICK PHARMACEUTICALS CORPORATION'S MOTION FOR SUMMARY JUDGMENT AS TO CLASS 2 CLAIMS

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Schering-Plough Corporation ("Schering") and Warrick Pharmaceuticals Corporation ("Warrick") respectfully submit this memorandum in support of their motion for summary judgment on the claims asserted by Class 2.[1] While the Class 2 claims against Schering and Warrick involve six drugs, the vast majority of the alleged damages (93%) are attributable to albuterol, which includes the generic albuterol produced by Warrick (86% of the total alleged damages) and also includes the branded albuterol (known as Proventil) produced by Schering (7% of the total). Accordingly, the focus of this motion is on albuterol, though many of the arguments apply equally to the other products that are at issue.

PRELIMINARY STATEMENT

The AWP system, which was created by government and private payers, has persisted as a pharmaceutical reimbursement method because it serves a number of useful functions. For that reason, plaintiffs cannot – and do not – allege that the system itself is inherently fraudulent. Some of its aspects are complex, with much of that complexity having arisen for disparate historical reasons. For the purposes at hand, however, it is important to note one feature that the system does *not* have: there is no statute or regulation defining AWPs. Additionally, as demonstrated below, there was no obligation on the part of pharmaceutical manufacturers, including Schering and Warrick, to report AWPs that were different from those AWPs published by the pricing compendia.

Notwithstanding the fact that there is no statutory definition of AWP, Plaintiffs allege in this case that defendants have subverted the AWP system by publishing AWPs that do not meet plaintiffs' arbitrary standard, *i.e.*, that for purposes of Medicare Part B reimbursement, AWP

[1] No subclass of Class 1 was certified as to Schering and Warrick. Consolidated Order re: Motion for Class Certification (Jan. 30, 2006) (Doc. No. 2097).

must equal the average sales prices ("ASPs") of the drugs in question. Reduced to its essence, Plaintiffs' claim is straightforward: Defendants allegedly inflated the AWPs to create and/or increase "spreads" between those AWPs and the actual costs of the drugs to providers in order to give providers an incentive to sell the drugs with the most inflated AWPs, thus resulting in increased profits and market shares for defendants. Third Amended Master Consolidated Complaint (Oct. 17, 2005) (Docket Nos. 1781-87) ¶¶ 3-4 ("TAMCC").

The fundamental – and fatal – flaw in plaintiffs' case as applied to multi-source drugs is simple as well: Plaintiffs' allegations directly contradict the reality of the generic or multi-source market. Not only was the generic market inconsistent with the Plaintiffs' allegations, but the particular conduct of Schering and Warrick in that market was also inconsistent with the Plaintiffs' allegations: the evidence shows that neither Warrick nor Schering engaged in any allegedly improper conduct as part of a purported AWP scheme. Specifically with respect to albuterol, the evidence shows that Schering and Warrick did not manipulate AWPs or market spreads to secure market share.

As discussed in the Declaration of Dr. Sumanth Addanki ("Addanki Decl."), Warrick and Schering

(1) did not have the economic incentive to manipulate their AWPs for albuterol to gain a competitive advantage;

(2) did not have the ability to manipulate their AWPs for albuterol to gain a competitive advantage; and

(3) did not in fact change their AWPs in a manner that manipulated, or attempted to manipulate, their AWPs for albuterol.

First, throughout the class period, Medicare reimbursed for multi-source products such as albuterol at the median AWP for the class of drug, not on the basis of the AWP of any individual drug. Therefore, a change in the median AWP for a class of drugs (such as albuterol)

would have altered the reimbursement rate for all drugs in the class uniformly, providing no competitive advantage to any particular manufacturer. Simply put, no incentive existed for any multi-source drug manufacturer to raise its AWP.

Second, unilaterally altering a median is extremely difficult. In fact, absent a conspiracy – which has not been alleged and for which there is absolutely no factual support – it is virtually impossible. Moreover, as a matter of historical fact, Warrick's AWPs for albuterol, in particular, were almost always *lower than* the median AWP for albuterol. Therefore, Warrick could not have been responsible historically for *increasing* the median AWP for albuterol – the essence of plaintiffs' allegations. Warrick simply could not have affected the reimbursement paid by the government or the co-payment amount paid by any member of class 2 (or class 1, for that matter) for albuterol. The same applies for different reasons with respect to Proventil, the branded form of albuterol manufactured by Schering. Ever since the introduction of generic albuterol, Proventil's AWP has always been higher than those of its generic competitors and therefore higher than their median. Consequently, reimbursement for Proventil was based on the median AWP, which was *below* Proventil's AWP. Further increasing Proventil's AWP would have made no impact on the median or Medicare reimbursement. Thus, for Schering's multi-source drug Proventil, just as for Warrick's generic albuterol, reality contradicts Plaintiffs' allegations. Neither Warrick nor Schering had the ability to alter the Medicare reimbursement rate for albuterol, generic or branded, during the period when albuterol was a multi-source drug.

Third, even assuming that it was possible to move the median at which albuterol was reimbursed, the actual conduct of Warrick and Schering refutes plaintiffs' allegations. It is undisputed that since 1995, shortly after entering the market, Warrick did not change the AWPs of its albuterol products. Warrick did not do anything with AWPs that could have affected

Medicare reimbursement for those products. During the same period, Schering consistently maintained a higher AWP for Proventil than its generic competitors, and likewise did nothing that could have affected the lower reimbursement provided for Part B albuterol. Indeed, in stark contrast to Plaintiffs' theory, Warrick achieved large market shares for albuterol with AWPs that were low in relation to its competitors, whereas Schering experienced low market shares for its branded version of the drug with higher AWPs.

Thus, with respect to albuterol, Schering and Warrick did nothing more than participate in an industry reimbursement system that was created by government and private payers and that reflected the impact of normal market forces and policy compromises. There is no evidence in this record five years in the making that supports an allegation – much less a conclusion – that Schering's or Warrick's actions in relation to albuterol can in any way be fairly characterized as deceptive or unfair. For these reasons, summary judgment for Schering and Warrick on Class 2 claims relating to albuterol is required. Plaintiffs must further proffer evidence that would justify continuing to proceed against Warrick or Schering as to any other drug.

STATEMENT OF FACTS[2]

The two Warrick products at issue for Class 2 in this litigation are albuterol solution and perphenazine, and only albuterol involves material sales.[3] Albuterol products have historically been the largest sellers for Warrick.[4] SOF ¶¶ 9-12. Albuterol is indicated for treatment of

[2] The material, undisputed facts relied upon in this Motion are attached hereto as Schering's and Warrick's Concise Statement of Undisputed Material Facts Pursuant to Local Rule 56.1 ("SOF").

[3] According to Plaintiffs' expert, albuterol accounts for more than 90% of total Class 2 damages. Addanki Decl. App. A.

[4] By contrast, perphenazine is a much smaller generic product for Warrick and is principally prescribed as an antipsychotic drug. SOF ¶ 14. It is occasionally – but rarely – used as an anti-emetic drug and therefore covered by Medicare Part B where so used. SOF ¶ 14. In fact, Medicare only paid approximately $50,000 during the entire class period for all perphenazine prescriptions, not just those manufactured by Warrick. Addanki Decl. n.2.

asthma and other respiratory ailments and is typically inhaled at home through a device called a nebulizer. SOF ¶ 6**.** Unlike most Medicare Part B drugs, albuterol is self-administered and generally obtained from a pharmacy, but it is covered under the "Durable Medical Equipment" provision of the Medicare statute. SOF ¶ 5. When prescribing generic albuterol, the prescribing physician does not specify the manufacturer of the albuterol to be dispensed. SOF ¶ 21.

Schering's Proventil, a branded form of the drug, was protected by patent until 1989. SOF ¶ 13. Warrick's generic version of the drug, which was among the first on the market, was introduced in 1993. SOF ¶ 13. Following introduction of the generic versions of albuterol, Schering has maintained relatively high AWPs for Proventil, but its market shares have been relatively low. Addanki Decl., Exs. 5A-B. By contrast, Warrick's AWPs for albuterol were consistently low in relation to its competitors, and Warrick has consistently achieved large market shares. Addanki Decl. ¶¶ 39, 43, Figures 2-3.

The two forms of albuterol at issue are the 0.083% solution and the 0.5% solution. Addanki Decl ¶ 43; SOF ¶ ¶ 4-6. Warrick initially established the AWPs for its albuterol products at 15-20% below the branded version of the drug, as is typical in the industry. SOF ¶¶ 35, 41. Since 1995, Warrick's AWPs for both forms of albuterol have stayed the same, year after year. Addanki Decl. ¶ 44, Exs. 4A-B; SOF ¶ 42.

Warrick did not market its albuterol products based on spread. SOF ¶¶ 47-49. It used a field sales force of only three representatives who dealt exclusively with the head offices of key accounts, plus some contract telemarketing support, to sell its products. SOF ¶¶ 52-53. Warrick competed in the marketplace based on the quality of its product, reliability of production and price. SOF ¶ 50. Once an account was established, Warrick maintained its business by meeting the prices offered by competitors. SOF ¶ 29.

Warrick's AWPs merely served as benchmarks used by the government and private payers within their reimbursement systems to achieve their policy objectives. At no time was Warrick aware of the Medicare reimbursement rate for albuterol, nor did it ever attempt to calculate the reimbursement rate. SOF ¶ 48. There is no evidentiary record whatsoever indicating that Warrick changed its albuterol AWPs in any manner that would have changed the median upon which reimbursement was based during the class period. Addanki Decl. ¶¶ 43-44. In fact, none of Warrick's albuterol AWPs have changed since 1995. Addanki Decl. ¶ 44, Exs. 4A-B.

Thus, no evidence suggests that Warrick or Schering manipulated the AWPs for albuterol and there is no evidence that Warrick or Schering marketed the spreads for albuterol. To the contrary, each company did exactly what public policy favors in a setting that the government and others created: it competed on the merits of its product line and on price.

ARGUMENT

I. THE STANDARD OF LIABILITY UNDER CHAPTER 93A

Plaintiffs assert their claims against Warrick and Schering pursuant to the Massachusetts consumer protection statute, Mass. Gen. Laws ch. 93A ("93A"), which provides three possible frameworks for proving liability.

First, a "per se" violation of 93A can be found in the event for failure to comply with statutes, rules, regulations, or laws providing for the protection of consumers. *Hershenow v. Enterprise Rent-A-Car Co. of Boston, Inc.*, 840 N.E.2d 526, 794-95 (Mass. 2006) (citing 940 Code Mass. Regs. § 3.16(3) (1993)).

Second, an act is deceptive "when it has the capacity to mislead consumers, acting reasonably under the circumstances, *to act differently* from the way they otherwise would have acted." *Aspinall v. Philip Morris Cos., Inc.*, 813 N.E.2d 476, 488 (Mass. 2004) (emphasis

added). However, there is no 93A liability if no one is actually deceived. *See, e.g., Kazmaier v. Wooten*, 761 F.2d 46, 51 (1st Cir. 1985) (affirming summary judgment on basis, *inter alia*, that plaintiff was not deceived); *Pump, Inc. v. Collins Mgmt., Inc.*, 746 F. Supp. 1159, 1173 (D. Mass. 1990) (affirming summary judgment for defendant on 93A claim based, *inter alia*, on finding that "[s]urely [plaintiff] was not fooled"). The threshold for establishing that conduct is deceptive is considerably higher in cases involving sophisticated entities.[5] *USM Corp. v. Arthur D. Little Sys., Inc.*, 546 N.E.2d 888, 898 (Mass. App. 1990) (affirming judgment that no unfair or deceptive acts exist when plaintiff, "a sophisticated business entity . . . was not misled").

Third, an act is unfair if it (a) "offends public policy as it has been established by statutes, the common law, or otherwise whether, in other words, it is within at least the penumbra of some common-law, statutory, or other established concept of unfairness"; (b) "is immoral, unethical, oppressive, or unscrupulous"; or (c) "causes substantial injury to consumers (or competitors or other businessmen)." *Berenson v. Nat'l Fin. Servs., LLC*, 403 F.Supp.2d 133, 149 (D. Mass. 2005). To prevail, however, Plaintiffs must show that defendants' conduct rises to the "level of rascality" or has a "rancid flavor of unfairness" under § 11.[6] *Commercial Union Ins. Co. v. Seven Provinces Ins. Co. Ltd.*, 217 F.3d 33, 40 (1st Cir. 2000); *Knapp Shoes v. Sylvania Shoe Mfg. Corp.*, 72 F.3d 190, 200 (1st Cir. 1995) (noting that the showing of rascality is "especially difficult" when the transaction involves "sophisticated business entities").

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[5] Even under § 9, the representation must be deceptive to those "acting reasonably under the circumstances." *Aspinall*, 813 N.E.2d at 487 (describing standard as the "likely reaction of a reasonable consumer rather than an ignoramus"); *see also Commonwealth. v. AmCan Enters., Inc.*, 712 N.E.2d 1205, 1209 (Mass. App. Ct. 1999) (describing standard of deceptiveness as "construed in the context of a reasonable consumer").

[6] Section 11 applies because these third party payors acted in a business context and were engaged in trade or commerce when they paid physicians for drugs purchased by their insureds. *See In re Pharm. Indus. Average Wholesale Price. Litig.*, 230 F.R.D. 61, 86 (D. Mass. 2005) (discussing Class 2 and noting that "corporations may bring class action claims" under § 11).

Moreover, the fairness of conduct may be judged according to industry standards. *Commercial Union,* 217 F.3d at 43-44 (affirming judgment that reinsurer had engaged in unfair conduct under 93A based on, *inter alia*, expert testimony regarding "the traditional mores of the industry"); *Salisbury v. Monumental Life Ins. Co.*, 1 F. Supp. 2d 97, 103 (D. Mass. 1998) (Saris, J.) (on summary judgment, denying 93A claim for unfair and deceptive settlement practices based, *inter alia*, on "the general nature of the policy as group life insurance as understood under industry (albeit not statutory) standards"); *James L. Miniter Ins. Agency, Inc. v. Ohio Indem. Co.*, 112 F.3d 1240, 1251 (1st Cir. 1997) (finding no 93A unfairness when insurer "adhered to the industry custom"); *Govoni & Sons Constr. Co., Inc. v. Mechanics Bank*, 742 N.E.2d 1094, 1107 (Mass. App. Ct. 2001) (finding no unfairness when procedures were "widely utilized by similar banks in the area"); *USM Corp., 546 N.E.2d at 898* (finding that reporting practice of seller was "in conformity with accepted methods within the business community"). Indeed, a § 11 claim applies "the standard of the commercial marketplace." *Commercial Union Ins.*, 217 F.3d at 40 (internal citations omitted).

Finally, to recover under 93A, Plaintiffs “must prove 'but for' causation and proximate causation." *Markarian v. Connecticut Mut. Life Ins. Co.*, 202 F.R.D. 60, 68 (D. Mass. 2001) (internal citation omitted). This is essential for any 93A claim. *See Hershenow, 840 N.E.2d at 534 n.20* (distinguishing between reliance and causation); *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. at 86 ("[W]hile [the plaintiff] need not show actual reliance on the misrepresentation, the evidence must warrant a finding that a causal relationship existed between the misrepresentation and the injury.") (quoting *Heller Fin. v. Ins. Co. of N. Am.*, 573 N.E.2d 8, 13 (Mass. 1991)); *Hartford Cas. Ins. Co. v. New Hampshire Ins. Co.*, 628 N.E.2d 14, 19- 20 (Mass. 1994) (holding that “any claim of an unfair act or practice, lacking a causal link,

failed"). Indeed, courts have consistently rejected 93A claims where the alleged harm cannot be adequately traced to the defendant's conduct. *See, e.g., States Res. Corp. v. The Architectural Team, Inc.*, 433 F.3d 73, 85 (1st Cir. 2005) (affirming denial of motion to amend to add 93A claim when plaintiff's alleged loss was "not a result of [defendant mortgagee's] conduct, but is a consequence of the foreclosure process and its requirements"); *RSA Media, Inc. v. AK Media Group, Inc*., 260 F.3d 10, 15-16 (1st Cir. 2001) (affirming summary judgment against plaintiff based on finding that harm was caused not by defendant's conduct, but "because of the Massachusetts regulatory scheme that prevents new billboards from being built").

As demonstrated below, Plaintiffs' claims fail all three theories of liability under Chapter 93A.

II. THERE IS NO STATUTORY OR REGULATORY BASIS FOR FINDING *PER SE* LIABILITY OR DECEPTION UNDER CHAPTER 93A

A. There Is No Statutory or Regulatory Basis for Per Se Liability

As demonstrated in the Track 1 Defendants' Joint Memorandum in Support of Summary Judgment ("Joint Memorandum"), Plaintiffs' argument that Warrick's and Schering's AWPs were required to equal average sales prices ("ASPs") "by statute" is contrary to the entire regulatory and legislative history of the Medicare Act.[7] Accordingly, any argument that defendants committed a *per se* violation of Chapter 93A by reporting average wholesale prices that were not equal ASP must fail.[8]

[7] Schering and Warrick adopt and incorporate by reference all arguments presented in the Joint Memorandum.

[8] Plaintiffs' contention that AWP equals ASP is untenable for the additional reason that, in calculating the damages that purportedly flow from the alleged misconduct, Dr. Hartman uses manufacturers' price, not wholesale price, as his "ASP". *See* Addanki Decl. ¶¶ 17-24. Nothing in the history of Average Wholesale Price litigation supports any theory that defendants' AWPs were deceptive or unfair because they did not reflect manufacturers' prices. Indeed, such an argument is inherently unreasonable because equating AWP with wholesale prices would squeeze all profit out of pharmaceutical distribution channels. Addanki Decl. ¶¶ 22-24. On the other hand, if middlemen are acknowledged to make a profit on their activities, as surely they must be in any economically and politically

B. The Regulatory and Legislative History of the Use of AWP by Medicare Belies the Contention that the Government was Deceived

As demonstrated in the Joint Memorandum, any argument that Class 2 members were injured because the government was deceived by Warrick's and Schering's AWPs must also fail. The publication of AWPs greater than ASPs was not deceptive because the government knew throughout the class period that AWPs did not have a formulaic relationship to ASPs. In fact, the government had actual knowledge of significant spreads between AWPs and acquisition costs. Because the government is obviously sophisticated, the threshold for establishing that defendants' conduct deceived the government is much higher. *See, e.g., USM Corp.*, 546 N.E.2d at 898. Since the only entity that could have been misled in an actionable way as to the Class 2 claims was the federal government, and since the evidence indisputably demonstrates that the government knew that no such formulaic relationship existed, there can be no liability for deception.[9]

Plaintiffs' suggestion that Warrick should have been reporting its actual *wholesale* prices (according to Dr. Hartman, ASPs) as its AWPs for purposes of Medicare reimbursement is particularly other-worldly. For the generic drugs manufactured by Warrick, many variables would affect wholesale ASP in a variety of ways that defy meaningful calculation. SOF ¶ 65**.** For example, Warrick's contracts with customers contain a "right of first refusal," which allows Warrick to meet any lower price that a competitor might offer on a generic product within a

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viable account of the pharmaceutical market, there must be a distinction between ASP and provider's acquisition cost that is not taken into account by the Plaintiffs and Dr. Hartman.

[9] The government had deep and specific knowledge about the spreads between AWP and acquisition costs for albuterol, Warrick's largest product. Between 1996 and 2002, the Office of Inspector General for the Department of Health and Human Services published no fewer than *six* full reports exclusively dedicated to explaining how AWPs for albuterol exceeded acquisition costs for albuterol by significant margins. *See* SOF at ¶¶ 67-72 (collecting government reports); Addanki Decl. ¶ 36, Exs. 3A-B.

specified period of time *following a sale*. SOF ¶ 24. Such a provision, if exercised by Warrick, would oblige Warrick to rebate to the customer the difference between what the customer paid for a product and the new price under the right-of-first-refusal for all product in the customer's system at the time the right is exercised. SOF ¶ 24. Furthermore, on the introduction of a generic product, Warrick and other generic manufacturers offer extended payment terms (30 or 60 days) and agreements to "reset" the price of all product purchased during that period at the price existing in the marketplace 30 or 60 days after launch. SOF ¶ 31. Thus, it is not until well after a product is sold that the amounts due under most rebate programs can be assessed and rebates paid. SOF ¶¶ 33. In addition, "auto-substitution programs" – utilized by wholesalers – must also be taken into account. Pursuant to these programs, pharmacies agree to take whichever manufacturers' generic a wholesaler supplies in exchange for a lowest-price guarantee. SOF ¶ 23. Since Warrick and a wholesaler cannot know how much product will be sold under such programs at the time the product is shipped and billed, the price concessions demanded by wholesalers on the preferred position within auto-substitution programs is given by a post-sale rebate. SOF ¶ 32. Simply put, the wholesale ASP used by Dr. Hartman is not a known quantity at the time sales that will ultimately be reimbursed under Medicare Part B are made. Consequently, in the absence of a consistent regulatory regime dictating how to address these and myriad other complexities, listing an AWP that is equal to a wholesale ASP prior to such sales is not feasible.

III. THERE IS NO EVIDENCE THAT WARRICK OR SCHERING ENGAGED IN UNFAIR OR DECEPTIVE CONDUCT IN CONNECTION WITH ALBUTEROL

Plaintiffs allege that Warrick and Schering acted unlawfully by intentionally manipulating AWPs to manipulate spreads on albuterol. TAMCC ¶ 177. Plaintiffs further allege that Warrick and Schering encouraged customers to purchase their products based on how much

more money they could make by buying and getting reimbursed for Warrick and Schering drugs compared to competing drugs. *See, e.g.*, TAMCC ¶ 632(e). Yet, despite years of litigation, dozens of depositions, and the production of millions of pages of documents, Plaintiffs can present no evidence to support these claims against either Warrick or Schering, let alone sufficient evidence to meet 93A's exacting standard. As shown below, Warrick and Schering participated in a Medicare reimbursement system created by the government and engaged in routine business practices in the sale of albuterol permitted within that system.

A. Albuterol Was A Multi-Source Drug During Most of the Class Period

The generic market differs significantly from the brand market, and context plays an important role in evaluating 93A claims. *See Kerlinsky v. Fidelity & Deposit Co.*, 690 F.Supp. 1112, 1119 (D. Mass. 1987), *aff'd*, 843 F.2d 1383 (1st Cir. 1988) ("[I]t is not the definition of an unfair act which controls, but the context -- the circumstances to which that single definition is applied"); *Cummings v. HPG Int'l, Inc.*, 244 F.3d 16, 25 (1st Cir. 2001) (noting that the "context" in which an unfair act is alleged "is of great import."). Unlike the brand market, in the generic (or multi-source) market, the competing products are identical. SOF ¶ 17. When a patient presents a prescription for albuterol, for example, the version of the product actually dispensed depends upon the pharmacy and the version it has chosen to carry. SOF ¶¶ 19-22; Addanki Decl. ¶¶ 31-32. Typically, a pharmacy carries only one version of a generic product. SOF ¶ 19. Moreover generic manufacturers typically compete for business by competing on price**.** SOF ¶¶ 29, 50; Addanki Decl. ¶¶31-32.

B. Relatively Large Spreads Are Typical of the Generic Market, But Plaintiffs' So-Called "Mega-Spreads" Are a Misnomer

Given the presence of perfect product substitutes in the generic market, prices change often and generally decrease over time. Addanki Decl. ¶¶ 27-32; SOF ¶¶ 18, 28. In the generic

market, there is no customary relationship between AWP and actual prices; instead, it is generally accepted that the AWP of the generic version of a branded product should be established initially at about 10-20% below the brand product's AWP. SOF ¶ 35.[10] Accordingly, while spreads between published AWPs and market prices have generally increased in the generic industry over the last decade, that is due for the most part to falling prices, not to increasing AWPs. Addanki Decl. ¶¶ 31-32.

Plaintiffs exaggerate the spreads in the generic market by calculating them in a misleading way and then labeling them "mega-spreads." The convention in calculating spreads – including the method used consistently by the government in its many reports – is to express the difference between AWP and ASP as a percentage below AWP. Addanki Decl. ¶¶ 35-36; SOF ¶ 25. Plaintiffs, however, express spreads as percentages above ASP. Addanki Decl. ¶ 33; SOF ¶ 26. This simple trick causes enormous distortions in the apparent magnitudes of spreads. For example, Plaintiffs have argued that the government was not aware of "mega spreads" on albuterol of up to 529%. *See, e.g.*, TAMCC ¶ 494. Plaintiffs' calculation, however, is based on a markup from ASP and not a markdown from AWP, contrary to convention. In 1998, spreads as high as 85% of AWP, or approximately 550% of "ASP," were reported publicly. Addanki Decl. ¶ 36. Comparing apples to apples mathematically, the spread that the government reported was comparable to that highlighted by the Plaintiffs. Therefore, Plaintiffs' "mega spread" calculations are entirely misleading.

[10] Thus, Warrick set its AWPs for albuterol at launch at 15%-20% below the branded AWP. Addanki Decl., Exs. 4A-B.

C. Contrary to Plaintiffs' Theory, No Correlation Exists Between AWPs and Market Shares for Warrick and Schering Albuterol

Plaintiffs have repeatedly asserted that drug manufacturers including Warrick and Schering intentionally manipulated AWPs to increase market share and gain a competitive advantage with respect to albuterol. *See, e.g.*, TAMCC ¶¶ 195-203. The facts refute these allegations. Warrick maintained relatively low AWPs for its albuterol products when compared with its competitors. Addanki Decl. ¶ 39, 43, Figures 2-3. Despite maintaining low AWPs, Warrick often enjoyed a large share of the market. Addanki Decl. ¶¶ 43-44. Moreover, when Warrick's market share began declining, it did not adjust its AWPs.[11] Addanki Decl. ¶45. In the case of Schering, while the Proventil AWPs were relatively high, as were its prices (ASPs), its market shares were consistently low. Addanki Decl. Exs. 5A-B.

D. Because Multi-source Albuterol was Reimbursed by Medicare Using a Median AWP, Warrick and Schering Had No Economic Incentive, and No Capacity, To Affect Medicare Reimbursement Rates by Manipulating AWPs

Medicare based its reimbursement for multi-source drugs on the median AWP of the products within the class of drug. SOF ¶ 63. Albuterol was a multi-source drug for the entire period for which Plaintiffs' have calculated damages. SOF ¶ 7.[12] This regulatory feature of the system entirely undercuts Plaintiffs' theory of liability and causation.

1. Warrick and Schering Had No Incentive to Engage in the Alleged Deceptive and Unfair Activity

Warrick and Schering could not have gained a competitive advantage by manipulating the AWPs for their albuterol products. Raising the median AWP would change the reimbursement rate for *all of the competitors' drugs as well.* Addanki Decl. ¶ 40 In other words,

[11] The data also show that when an albuterol competitor *lowered* its AWP in 2002, its market share *increased*. Addanki Decl. ¶45.

[12] Generic albuterol was launched in 1993. SOF ¶ 13.

the alleged spreads between ASP and reimbursement rate would increase equally, thereby creating no economic incentive to purchase one form of the drug over another. Addanki Decl. ¶ 40. Hence, Warrick had no incentive to manipulate AWP to affect spread in the generic/multi-source market, undercutting the basic assertion of Plaintiffs' theory.

2. Warrick and Schering Lacked the Ability to Inflate the Median AWP

Even if Warrick or Schering had (irrationally) wanted to affect the median, the information necessary to do so was unavailable. During the Class Period, the median reimbursement rate was set separately by four regional Medicare carriers. The precise methodology by which each carrier calculated the median was unknown and the reimbursement rate was not published. SOF ¶ 8.

Even if (contrary to fact) the median were a known quantity, elementary mathematics dictates that it is extremely difficult, if not impossible, for an individual company to affect the median by manipulating its AWPs. Addanki Decl. ¶¶ 41-42. A median, by definition, is the value in a given set of values above and below which there are an equal number of values. It is not an average. Addanki Decl. ¶¶ 41-42. For example, if the AWPs at issue were $1, $4, $8, $9, and $10, $8 is the median AWP even though the average AWP would be lower. A change to one of the values only affects the median if that change affects the number of values above or below the median. As a result, changes to individual values in a given set often do not result in a change to the median. Addanki Decl. ¶¶ 41-42. In the example given, $8 is still the median even if the $4 AWP is lowered to $1. In other words, a change in one AWP for a generic product will not affect the median AWP unless that change so happens to alter the number of AWPs above or below the middle AWP. Thus, Plaintiffs' allegation that "any one generic manufacturer can . . . effect [sic] the median generic reimbursement AWP for a product," TAMCC ¶ 202, contradicts basic mathematics. Addanki Decl. ¶¶ 41-42. Indeed, in his

deposition, Dr. Hartman did not support this allegation by Plaintiffs. Transcript of Deposition of Raymond S. Hartman at 1370-87, the relevant portions of which are attached to the Declaration of Eric P. Christofferson ("Christofferson Decl.") as Ex. 22. He testified that, if a generic product's AWP is below the median AWP of all forms of the product, the manufacturer could not have caused any damages. *Id*. at 1386-87.[13]

3. There is No Evidence of Any Change in a Warrick or Schering AWP that Could Have Inflated the Median

Mr. Weintraub, who set prices on behalf of Warrick at all the relevant times, testified that at no point did he know the actual reimbursement amount for albuterol. SOF ¶ 48. He never attempted to calculate the Medicare reimbursement rate, nor did he ever attempt to use it in making pricing decisions. SOF ¶ 48. Indeed, the record shows unambiguously that Warrick raised the AWP of its albuterol only twice in 1995 and then never changed it. Addanki Decl. ¶ 44, Exs. 4A-B. With respect to Proventil, it is undisputed that Schering, whose AWPs always exceeded the median, never made any effort to alter the AWP in order to affect the Medicare reimbursement rate for its product. Addanki Decl. Exs. 5A-B. Given the implausible theory that Plaintiffs have presented, there is simply no evidence suggesting that Warrick or Schering could reasonably foresee how its AWPs would affect the Medicare reimbursement rate.

E. There is No Evidence that Warrick or Schering Marketed the Spread for Albuterol

1. Warrick

[13] Since increasing an AWP that is above the median does not raise the median, it follows that Plaintiffs cannot demonstrate a causal connection between the unfair act and the damages alleged. *Polycarbon Indus., Inc. v. Advantage Eng'g, Inc.*, 260 F. Supp. 2d 296, 306 (D. Mass. 2003) ("[T]o prevail on a Chapter 93A claim, plaintiff must show causal connection between defendant's unfair and deceptive act and damage suffered and that such damage was reasonably foreseeable.") (citing *Shepard's Pharm., Inc. v. Stop & Shop Cos*., 640 N.E.2d 1112 (Mass. App. Ct. 1994)

Plaintiffs can provide no evidence that Warrick marketed the spread. Warrick's marketing was lawful and effective. It used a field sales force of only three to four representatives, plus some contract telemarketing support, to sell its products. SOF ¶¶ 52-53. Moreover, as a practical matter, Warrick could not have marketed the spread for albuterol because its AWPs for its albuterol products were generally substantially lower than its competitors. Addanki Decl. ¶ 39, Figures 1-3. In other words, because Warrick was not manipulating its AWPs, it could not take advantage of any AWP inflation in its marketing even if it had wanted to do so.

Nevertheless, Plaintiffs have alleged that Warrick was "[e]ncouraging Medicare Part B providers to use drugs based upon the 'spread' as opposed to medicines being prescribed based on medical reasons." TAMCC ¶ 632(e). But, unlike Plaintiffs' theories about incentives with respect to branded PADs, Plaintiffs' allegations in the context of self-administered generic drugs such as albuterol at best address attempts to create indirect incentives. A prescribing physician does not designate which manufacturer's version of a generic self-administered drug is dispensed. SOF ¶ 21. In addition, as a result of the auto-substitution programs discussed earlier, the pharmacist often does not decide which version of the generic it stocks. SOF ¶ 23.

Moreover, no document or testimony suggests that Warrick was marketing the spread. Instead, to support its claim, Plaintiffs rely on periodic price notifications Warrick sent to its customers, and assert that these documents somehow demonstrate Warrick's deceptive conduct in "touting" its spreads. *See, e.g.*, TAMCC ¶ 494. These price notifications simply listed the name of the product, its package size, its NDC, its AWP, and its "direct price," i.e., the price to the customer.

Although Plaintiffs suggest that these notifications constitute marketing the spread because customers *could* calculate the spread between the AWP and direct price and *could* compare that to a competitor's spread, there is no evidence that Warrick instructed them to do either of those things. The fact that Warrick provided an AWP with its direct price is irrelevant since AWPs were publicly available from pricing compendia. More importantly, Warrick's AWP was *not* the basis upon which Medicare reimbursed the providers. Therefore, the information contained in Warrick's price notifications was *not* sufficient for Warrick's customers to calculate the spread on Warrick's albuterol products, much less compare such a spread to a competitor's spread. Plaintiffs just assume that (a) customers had analogous information from competitors on which to make a comparison, and (b) that the customers, *i.e.*, the pharmacies, knew what the median AWP (reimbursement rate) was for all forms of the drug, because Warrick communicated no such information. Plaintiffs have no evidence to support any such bald inferences.

In other words, if simply sending a price list constitutes evidence of marketing the spread, then *any* time *any* manufacturer tells a customer its price, that manufacturer has marketed the spread, because the customer *could* calculate the spread based on already publicly available AWPs and *could* compare it to a competitor's spread. Therefore, unless some manufacturers never tell customers the prices they charge for their products – a premise that strains all credulity – then every pharmaceutical manufacturer "markets the spread" regularly, *i.e.*, whenever it tells a customer the product's price. Plaintiffs' arguments require unsupported inferences that should be ignored. *Burke v. Town of Walpole*, 405 F.3d 66, 76 (1st Cir. 2005) (holding that "conclusory allegations, improbable inferences, and unsupported speculation" may be ignored) (citation omitted)). Either the Plaintiffs' definition of marketing the spread is grossly overbroad or

Warrick's publishing of price notifications is insufficient to meet it. In any event, there is no evidence that Warrick marketed the spread.

2. Schering

Plaintiffs' purported "evidence" demonstrating that Schering manipulated AWPs and marketed the spread does not rest on specific facts, as required, but rests solely on allegations and inferences.[14] Among the millions of pages of materials that Schering and Warrick produced, Plaintiffs have proffered only three documents to attempt to prove a vast scheme to manipulate AWPs. These documents show nothing of the kind.[15]

In Plaintiffs' Motion to Supplement the Record regarding class certification, Plaintiffs suggested that two documents constitute evidence of Schering's AWP manipulation. Pls.' Supplemental Factual Authorities Based on New Evidence Submitted in Support of Pls.' Motion for Class Certification (Doc. No. 1606) (Jul. 21, 2005). They do not. Not only do these documents have nothing to do with manipulating AWPs, neither concerns a drug at issue in this litigation. [16] Moreover, in their TAMCC, Plaintiffs cite to a memorandum from a senior vice

[14] One of Plaintiffs' experts draws an obviously false deduction to conclude that Schering was manipulating spreads. In her liability report, Dr. Rosenthal refers to a chart purporting to demonstrate the spread on an Intron-A product over time. Although she states that the spread increased over the entire period, her conclusion is belied by the data. In fact, the data showed that the spread actually declined over some portions of the time period, and Dr. Rosenthal was forced to retract her conclusion at her deposition when confronted with this problem. Transcript of Deposition of Meredith Rosenthal (February 23, 2006) at 290-300, the relevant portions of which are attached to Christofferson Decl. as Ex. 23.

[15] Schering produced thousands of call notes in this case, which are notes that sales representatives used to memorialize their meetings and conversations with physicians in the course of selling Schering's products. SOF ¶ 61. Neither the call notes nor the testimony provided by any of the four sales representatives deposed suggests that Schering or Warrick was marketing the spread. SOF ¶ 58. The sales representatives explained that discussions about reimbursement with physicians were rare and were primarily limited to answering questions about the mechanics of the Medicare reimbursement process by physicians who had not participated in the Medicare program. SOF ¶ 62 (summarizing depositions of sales representatives). Plaintiffs cannot carry this burden.

[16] Appendix A.4, notwithstanding that it is a document without any context or author, is a hypothetical illustration showing that AWP-based reimbursement for a generic drug can simultaneously result in a greater margin for the pharmacy and a lower reimbursement cost to the payer than can the brand version of the drug. Pls.' Mot. to Supplement the Record at app. A.4. In other words, it merely shows that generics provide savings to everyone,

president of Schering about the generic launch of albuterol. TAMCC ¶ 493. The only inference about prices to be drawn from the document is that Schering chose *not* to alter its AWPs upon the launch of another product. Plaintiffs do not and cannot argue that this document demonstrates manipulation of AWP. Not only are these few documents insufficient to establish a company-wide "scheme" to inflate and manipulate AWPs with respect to all drugs at issue over the entire class period, they provide no evidence of any specific *act* of AWP manipulation. Plaintiffs' mere conclusory statements to the contrary are insufficient to make them so. *See Burke*, 405 F.3d at 76.

IV. THE EVIDENCE IS INSUFFICIENT TO AVOID SUMMARY JUDGMENT ON THE PLAINTIFFS' IMPLAUSIBLE THEORY

A. Plaintiffs' Implausible Theory Demands More Proof than Plaintiffs Can Proffer

As indicated, the undisputed evidence shows that Warrick and Schering competed in the multi-source market for albuterol exactly as the law and the American economic system encouraged them to compete: by lowering prices. That conduct cannot be culpable under Chapter 93A or any other rule of law. As the Supreme Court has said in a different but analogous setting, where the antitrust laws were invoked to prevent price competition:

> [C]utting prices in order to increase business often is the very essence of competition. Thus, mistaken inferences in cases such as this one are especially costly, because they chill the very conduct the antitrust laws are designed to protect. "[We] must be concerned lest a rule or precedent that authorizes a search for a particular type of undesirable pricing behavior end up by discouraging legitimate price competition."

Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 594 (1986) (citations omitted).

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including Third-Party Payors, such as the members of Class 2. Appendix A.6 is an internal memo discussing the pros and cons (from Schering's perspective) of offering rebates on Claritin to unspecified "Medical Groups" in

Under 93A, Plaintiffs must prove that Schering and Warrick did something other than lower prices in response to competition that violated a legal duty, deceived the government, or fell within the penumbra of legal prohibitions to an extent justifiably labeled actionably unfair. *Tagliente v. Himmer*, 949 F.2d 1, 7 (1st Cir. 1991) (awarding summary judgment to the defendant where "the record show[ed] . . . that the defendant committed no acts so misleading or deceptive to warrant recovery for [the plaintiff] under chapter 93A"); *Baybank Middlesex v. 1200 Beacon Props., Inc.*, 760 F.Supp. 957, 970 (D. Mass. 1991) (granting summary judgment to defendants where plaintiffs submitted no evidence in support of their Chapter 93A claim "beyond . . . conclusory allegations and assertions"). Their proof must demonstrate *specific facts* constituting an actionable wrong; allegations and inferences will not "deflect the swing of the summary judgment scythe." *Mulvihill v. Top-Flite Golf Co.*, 335 F.3d 15, 19 (1st Cir. 2003).

Plaintiffs here have proffered nothing more than insinuations of conduct that is inconsistent with the market in which it was supposed to have occurred – manipulating spreads for a competitive advantage when no such advantage could possibly be obtained – or else the result of entirely lawful and laudatory price competition. When a plaintiff's theory is as implausible as the Plaintiffs' theory is here, the Supreme Court has imposed an unusually heavy burden on the plaintiff to avoid summary judgment. *Matsushita*, 475 U.S. at 587 (holding that "if the factual context renders respondents' claim implausible – if the claim is one that simply makes no economic sense – respondents must come forward with more persuasive evidence to support their claim than would otherwise be necessary").

California. *Id.* at A.6. The document makes reference to the "AWP price differential between Claritin and Allegra," but that reference has nothing to do with reimbursement.

Similarly, where the allegedly injured party is as sophisticated and knowledgeable as the federal government is in the realm of Medicare reimbursement for prescription drugs, 93A demands more to avoid summary judgment than might usually suffice; they must come forward in opposition to summary judgment with evidence that is beyond the inferences upon implausible inferences that the Plaintiffs have adduced here. *See, e.g., Romani v. Cramer, Inc.*, 992 F.Supp 74, 81 (D. Mass. 1998) (granting summary judgment where "[p]laintiff's 'factual' assertions in opposition [were] too weak to reach the 'more than a mere scintilla' standard" required by the First Circuit) (citations omitted); *Mastoran Rest., Inc. v. Commonwealth of Mass. Div. of Capital Mgmt.*, 2001 WL 1811963, at *4 (Mass. Dist. Ct. Dec. 31, 2001) (granting summary judgment to defendants on plaintiff's Chapter 93A claim where plaintiff's evidence consisted of a "string of inferences . . . too weak" to support plaintiffs' claim and holding that "[t]he ultimate fact upon which [the plaintiff's] claims are based . . . must be predicated on *evidence*, not speculation or surmise") (emphasis added).

Here, Plaintiffs' case against Warrick and Schering in relation to multi-source albuterol does not rise to the level of credible surmise; it is implausible as well as unsupportable. Therefore, summary judgment is warranted.[17, 18]

[17] Plaintiffs have asked for the Court to award punitive damages. TAMCC at p. 299. The standard for obtaining punitive damages under Chapter 93A, however, "contemplates a more purposeful level of culpability" and "the intentional employment of sharp practices." *Wasserman v. Agnastopoulos,* 497 N.E.2d 19, 24-25 (Mass. App. Ct. 1986). The Supreme Judicial Court has recognized that, in order to prove willful violations of Chapter 93A, the misrepresentation has to be "callous and intentional." *Heller v. Silverbranch Constr. Corp.*, 382 N.E.2d 1065, 1070 (Mass. 1978). Mere knowledge is not enough; there must be "something more." *Damon v. Sun, Co., Inc.*, 87 F.3d 1467 (1st Cir. 1996) (quoting *Cambridge Plating Co., Inc. v. Napco, Inc.*, 85 F.3d 752, 770 (1st Cir. 1996). Indeed, an offense may even be "grievous" without being "knowing or willful." *Shawmut Cmty. Bank, N.A. v. Zagami*, 568 N.E.2d 1163 (Mass. App. Ct. 1991), *rev'd in part on other grounds*, 568 N.E.2d 962 (Mass. 1992).

[18] Notwithstanding Plaintiffs' allegations regarding liability, their calculation of damages is flawed in several important ways. Schering and Warrick understand that the Court will consider issues related to damages at a later date. Therefore, the companies reserve their right to raise objections to Plaintiffs' calculations of damages at that time.

B. Plaintiffs Cannot Prove Causation, Which is an Indispensable Element of Their Claims

As discussed earlier, Plaintiffs "must prove 'but for' causation and proximate causation" to recover under c. 93A. *See, e.g., Markarian v. Connecticut Mut. Life Ins. Co.*, 202 F.R.D. 60, 68 (D. Mass. 2001) (internal citation omitted); *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. at 86 ("[W]hile [the plaintiff] need not show actual reliance on the misrepresentation, the evidence must warrant a finding that a causal relationship existed between the misrepresentation and the injury.") (quoting *Heller Fin. v. Ins. Co. of N. Am.*, 573 N.E.2d 8, 13 (Mass. 1991)). This they cannot do.

Because albuterol was a multi-source drug throughout the period that Plaintiffs claim they suffered damages, it was reimbursed by Medicare on the basis of the median AWP for all versions of albuterol on the market. As already demonstrated, Warrick and Schering had no incentive to affect the median, they had virtually no ability to do so, and as a matter of undisputed fact they did not do anything that had the effect of inflating the median. Therefore, no conduct of Warrick or Schering could possibly have caused any harm to the Plaintiffs in respect of generic albuterol or Proventil, and the Plaintiffs cannot make out a claim under 93A relating to either version of the multi-source drug.

V. CLAIMS PREDATING 1997 ARE BARRED BY THE STATUTE OF LIMITATIONS

Plaintiffs have failed to establish sufficient facts to justify tolling the four-year statute of limitations applicable to all 93A claims, for reasons set forth in the Joint Memorandum. That argument is particularly compelling as to albuterol. Albuterol has been the focus of six federal government reports, including two 1996 reports titled, "A Comparison of Albuterol Sulfate Prices" and "Supplier's Acquisition Costs for Albuterol Sulfate." SOF ¶¶ 67-68; *see also* Addanki Decl. ¶ 36, Ex. 3A-B. Moreover, as discussed in the Joint Memorandum, Class 2

payors themselves, including BCBSMA, made numerous purchases of the drug at prices below AWP. Actual knowledge of operative facts bars any claim that such facts were "inherently unknowable" or were "fraudulently concealed." *See, e.g., Estate of Sarocco v. Gen. Elec. Co.*, 939 F. Supp. 91, 97 (D. Mass. 1996). There is no evidence that Warrick concealed the existence of a claim. For albuterol purchases made before December 1997, Plaintiffs simply cannot "establish the facts that take their case 'outside the impact of the statute of limitations.'" *Zamboni v. Aladan Corp.*, 304 F. Supp.2d 218, 223 (D. Mass. 2004) (internal citation omitted). Thus, the statute of limitations bars any claims as to reimbursements for albuterol made before that time.

CONCLUSION

For the foregoing reasons, Schering and Warrick respectfully request that their motion for summary judgment as to Class 2 claims be GRANTED.

Schering-Plough Corporation and
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Dated: March 15, 2006

CERTIFICATE OF SERVICE

I hereby certify that on March 15, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Eric P. Christofferson_____
Eric P. Christofferson